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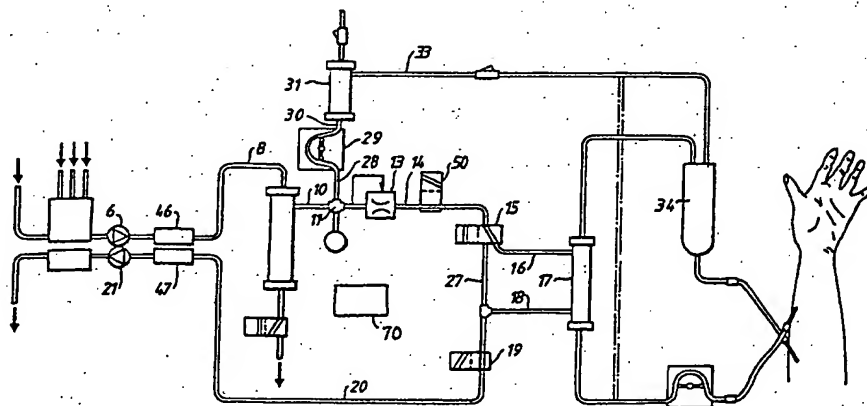
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(54) Method and device for monitoring an infusion pump

(57) Method and device for monitoring of an infusion pump in a machine for hemodiafiltration or hemofiltration. The machine comprises a first flow circuit for a dialysis solution with a flowmeter arranged in the flow circuit. In addition, there is a second flow circuit for blood. A dialyser or hemofilter is divided by means of a semi-permeable membrane into a first chamber which is connected to the first flow circuit and a second chamber which is connected to the second flow circuit. In addition, there is a third flow circuit from an outlet for

dialysis solution in the first flow circuit to a connection in the second flow circuit and comprising an infusion pump. The dialyser is disconnected by means of a valve from the first flow circuit so that the infusion pump is connected in series with the flowmeter in the first flow circuit. The monitoring of the infusion pump takes place by comparing the expected flow through the infusion pump with the measured flow through the flowmeter.

Fig. 2



EP 0 904 789 A2

Description

TECHNICAL FIELD

[0001] The present invention relates to a method and a device for monitoring an infusion pump in a hemodiafiltration machine or hemofiltration machine. More particularly, the invention relates to a method and a device for calibrating the infusion pump.

BACKGROUND OF THE INVENTION

[0002] A conventional type of hemodialysis machine is disclosed in EP-B1-278 100. Such a dialysis machine is marketed under the tradename GAMBRO AK 200 ULTRA and is adapted to perform hemodialysis, hemodiafiltration or hemofiltration treatment.

[0003] The dialysis machine prepares a dialysis solution comprising sodium-, bicarbonate-, potassium-, calcium-, magnesium-, chloride- and acetate ions in suitable concentrations, as well as possibly glucose and other ions, all dissolved in water. The concentrations of the ions in the dialysis solution are generally mirror-images of the concentrations in blood, where the mirror line is the normal concentration in blood of the ions. Thus, if an ion concentration is increased in the blood over the normal concentration, the ion concentration in the dialysis solution is decreased in relation to the normal concentration. The pH of the solution is adjusted to about 7.1-7.4.

[0004] In hemodialysis treatment, the solution is used to achieve dialysis in a dialyser. The dialyser is divided into two chambers by means of a semi-permeable membrane. Blood which is to be treated passes over one side of the membrane whilst the dialysis solution prepared by the dialysis machine passes over the other side. Diffusion of ions takes place through the membrane for conditioning the blood and to replace the function of the kidneys, at least partly. In addition, a quantity of liquid is removed from the blood since the patient is unable to get rid of surplus liquid in a normal manner. The removed liquid flowing through the membrane is called ultrafiltrate flow.

[0005] During hemodiafiltration, the ultrafiltrate flow is increased above that which is necessary to restore the liquid balance of the patient. As replacement, an infusion solution is added to the blood to permit the increased ultrafiltration flow.

[0006] During hemofiltration, substantially no dialysis takes place, but instead the blood is filtered, whereby a part of the ultrafiltration volume is added to the blood as infusion solution. The difference between the ultrafiltration volume and the added substitution volume constitutes the volume of liquid which is removed from the patient to restore the liquid balance. The infusion solution may be added upstream of the dialyser or hemofilter in a process called "pre-infusion", or downstream of the dialyser or hemofilter in a process called "post-infusion".

sion".

[0007] To effect the infusion flow, the dialysis machine comprises an infusion pump connected to an outlet for infusion solution on the dialysis machine. The infusion solution is normally the same as the dialysis solution. The infusion solution passes through the infusion pump and a sterile filter and is then fed to the patient's blood. The infusion pump may be a so-called peristaltic pump, as is used in the above-mentioned GAMBRO AK 200 ULTRA dialysis machine.

[0008] Prior to treatment, the dialysis machine is provided with a tube set, the constituent components of which must be filled with liquid so that all air is expelled. This normally takes place in a priming step during which sterile sodium chloride solution is fed into the various tubes and components of the tube set. The conduit system of the dialysis machine is also filled with dialysis solution.

[0009] During the priming of the infusion circuit, a dedicated deaeration conduit from the sterile filter is used so that the filter is completely filled with priming liquid so that the air is expelled. The nurse uses forceps or a tube clamp which is placed on the normal output conduit from the sterile filter and thereby cuts off the flow there-through. In addition, a tube clamp is opened in the deaeration conduit from the sterile filter. After deaeration of the sterile filter, the nurse removes the forceps from the output conduit or opens the tube clamp, as well as closing the tube clamp on the deaeration conduit, and the priming continues.

[0010] Due to the human factor, the nurse may forget to remove the forceps or to open the tube clamp, which may result in no infusion taking place. This may have serious consequences for the treatment if it is not corrected.

[0011] The infusion pump may be a peristaltic pump which is driven at a predetermined speed or number of revolutions so that a desired infusion flow or volume is attained. However, a peristaltic pump is sensitive to the pressure at the inlet and it may be desirable to calibrate the pump for the particular treatment and/or to check whether the desired infusion volume has actually been attained at a particular rotational speed of the peristaltic pump.

[0012] A peristaltic pump may exhibit leakage due to the fact that the occlusion of the pump segment is not complete, something which may result in zero flow.

[0013] In addition, problems may arise if the user installs a tube set which is not intended for the dialysis machine in question, for example a counterfeit copy, which may not provide a suitable infusion flow.

[0014] It may also be desirable to indicate if all air in the sterile filter has been completely expelled during the priming, or if there is a blockage or leakage in the sterile filter.

SUMMARY OF THE INVENTION

[0015] An object of the present invention is to provide a method and a device for permitting detection of the above-mentioned operational faults.

[0016] A further object is to provide a method and a device of the above-mentioned type in which substantially only components which normally form a part of a dialysis machine are used.

[0017] Accordingly, there is provided a method for monitoring an infusion pump in a machine for hemodiafiltration or hemofiltration. The machine comprises a first flow circuit for a dialysis solution; a flowmeter arranged in said first flow circuit; a second flow circuit for blood; a dialyser or a hemofilter which, by means of a semi-permeable membrane, is divided into a first chamber connected to the first flow circuit and a second chamber connected to the second flow circuit; a third flow circuit from an outlet for infusion solution in the first flow circuit to a connection in the second flow circuit and comprising an infusion pump. The method comprises the steps of disconnecting the dialyser from the first flow circuit; connecting the infusion pump in series with the flowmeter in the first flow circuit; and monitoring the infusion pump by comparing the expected flow through the infusion pump with the measured flow through the flowmeter. In this way, the infusion pump is calibrated with reference to the flowmeter.

[0018] In a preferred embodiment, the flowmeter is constructed as a double flowmeter having portions for measuring incoming and outgoing flows configured so that the flowmeter portion for incoming flow is connected in series with the infusion pump. Alternatively, the flowmeter may comprise an ultrafiltration metering pump.

[0019] As another alternative, the flow in the first flow circuit may bypass the dialyser or hemofilter via a bypass conduit, so that the flowmeter determines the difference between incoming flow and outgoing flow in the first flow circuit.

[0020] Moreover, there is provided a device for monitoring an infusion pump in a machine for hemodiafiltration or hemofiltration. The machine comprises a first flow circuit for a dialysis solution; a flowmeter arranged in said first flow circuit; a second flow circuit for blood; a dialyser or a hemofilter which, by means of a semi-permeable membrane, is divided into a first chamber connected to the first flow circuit and a second chamber connected to the second flow circuit; a third flow circuit from an outlet for infusion solution from the first flow circuit to a connection in the second flow circuit, comprising an infusion pump. According to the invention, the machine further comprises a first valve for disconnecting the dialyser from the first flow circuit and connecting the infusion pump in series with the flowmeter in the first flow circuit, and an arrangement for monitoring the infusion pump by comparing the expected flow through the infusion pump with the measured flow through the flow-

meter.

[0021] In a preferred embodiment, the first valve is arranged in a conduit which connects the outlet with the dialyser so that the flow in the first flow circuit ceases and all flow through the flowmeter also passes through the infusion pump.

[0022] Alternatively, the first valve is arranged in a conduit which connects the dialyser with the first flow circuit so that the dialyser is completely disconnected from the first flow circuit, whereby a second valve connects the dialysis flow via a bypass conduit past the dialyser. Moreover, there is an arrangement for monitoring the infusion pump by comparing the expected flow through the infusion pump with the difference between incoming and outgoing flows through the flowmeter.

[0023] In another embodiment, the flowmeter comprises an ultrafiltration pump which supplies liquid to the first flow circuit; and in that the inlet flow and outlet flow in the first flow circuit are equal.

[0024] Further objects, features, advantages and properties of the method and the device according to the invention will become apparent from the following description of preferred embodiments of the invention with reference to the attached drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025]

Fig. 1 is a schematic diagram of a dialysis machine of conventional construction in which the invention may be applied.

Fig. 2 is a diagram corresponding to Fig. 1 modified according to a first embodiment of the invention.

Fig. 3 is a diagram according to Fig. 1 modified according to a second embodiment of the invention.

Fig. 4 is a schematic diagram corresponding to Fig. 1 modified according to a third embodiment of the invention in which the invention is applied to a dialysis machine with a separate ultra filtration pump.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0026] Fig. 1 shows a schematic diagram of a part of a dialysis machine, for example of the GAMBRO AK 200 ULTRA type.

[0027] The dialysis machine in Fig. 1 comprises an inlet 1 for pure water, normally obtained from an RO-unit. In addition, a preparatory unit 2 is provided for preparation of a dialysis solution of desired composition from one or more concentrates denoted by arrows 3, 4 and 5. The preparatory unit 2 is conventional and thus will not be described in further detail.

[0028] A pump 6 feeds the dialysis solution via a flowmeter 7 and via a first conduit 8 to a first filter 9. The filter 9 is a filter which is used for multiple treatments and has a large surface area. The filter 9 passes sub-

stances, molecules and ions below a certain predetermined size, for example below a diameter of 5 nm.

[0029] The filtered dialysis solution flows along a conduit 10 to an outlet 11 from which an infusion solution may be removed. A conduit 12 extends from the outlet 11 to a throttle valve 13 which ensures that the pressure upstream of the throttle valve is substantially constant, for example +50 mmHg. A conduit 14 extends from the throttle valve 13 to a switching valve 15 and further via a tube 16 to a dialyser 17. A conduit 18 extends from the dialyser 17 to a valve 19. A conduit 20 extends from the valve 19 back to the flowmeter 7. The dialysate flows through the flowmeter and via a pump 21 and further devices 22 to an outlet 23.

[0030] The flowmeter 7 consists of two portions or channels 46 and 47 so that incoming and outgoing flow may be measured separately. In addition, an accurate value of the difference between the outgoing and incoming flow may be obtained, which difference normally corresponds to the ultrafiltrate flow which is removed in the dialyser 17.

[0031] A conduit 24 extends from the filter 9 via a valve 25 to an outlet 26.

[0032] A bypass conduit 27, which bypasses the dialyser 17, extends between valves 15 and 19.

[0033] A conduit 28 extends from the outlet 11 to a peristaltic pump 29 and further via a conduit 30 to a sterile filter 31. A conduit 32 for deaeration of the sterile filter is connected to the other end of the sterile filter. In addition, a conduit 33 is provided which extends from the sterile filter to a drip chamber 34. The sterile filter 31 is normally used once and is sterilised before use.

[0034] The dialysis machine also comprises an extracorporeal flow circuit for blood. From, for example, a fistula located in the patient's arm 35, blood is removed from the body via an artery needle 36 which, via conduit 37 and a peristaltic pump 38, extends to the lower end of the dialyser 17. From the upper end of the dialyser, the conditioned blood is transferred via a conduit 29 to the drip chamber 34 where it is deaerated and returned to the patient via a conduit 40 and a venous needle 41.

[0035] The above-described flow circuit is a conventional flow circuit arranged for post-infusion. Alternatively, the conduit 33 may be connected as shown by the dashed line 41 to an inlet point 42 between the pump 38 and the dialyser 17 to thereby attain pre-infusion.

[0036] When the dialysis machine is operated for hemofiltration treatment, the valve 15 is switched such that the conduit 16 is disconnected and the dialyser 17 is connected to the dialysis machine solely via the conduit 18. In this case, the dialyser 17 is exchanged for a hemofilter, which has no connector for conduit 16.

[0037] The dialysis machine comprises a computer 70 adapted to control and monitor the operation of the different components of the machine. Thus, the computer operates the valves and pumps, and receives signals from valves and pumps indicating the positions and conditions thereof, as well as signals from the various

meters.

[0038] During priming of the sterile filter 31, a nurse closes a conventional tube clamp 43 on tube 33 as shown in Fig. 1 and opens a conventional tube clamp 44 on the deaeration conduit 32. The dialysis solution which is pumped by the pump 29 will thus pass through the sterile filter 31 and fill it with liquid, as well as expel the air in the filter via the deaeration conduit 32, which is open to atmosphere. When all the air has been expelled, tube clamp 44 is closed and tube clamp 43 in the conduit 33 is opened and any air which may remain in the filter and conduit 33 passes via conduit 33 to drip chamber 34.

[0039] There are a number of errors which would be desirable to detect in such a system.

[0040] For example, the nurse may forget to open the tube clamp 43 in the conduit 33 so that it is blocked at the same time that the tube clamp 44 on the conduit 32 is closed. Should this happen, the peristaltic pump 29 cannot pump any liquid or infusion solution, so that no infusion solution reaches the patient.

[0041] As a further example, if the sterile filter is not thoroughly deaerated, the infusion flow may be too low. Should blockage or leakage in the filter arise, the situations needs to be remedied.

[0042] It is also desirable to be able to calibrate the infusion pump 29 during the treatment, or at least at the commencement of the treatment.

[0043] It is further desired to detect a leakage in the pump due to the pump segment not being completely occluded.

[0044] It is still further desirable to detect if an unsuitable tube set is used as it may result in malfunction with resulting erroneous infusion flow.

[0045] All of these malfunctions may be detected by the invention as described below. It will be understood by the skilled person that the operation according to the invention may be controlled and monitored by the dialysis machine computer 70.

[0046] According to the invention, a cut-off valve 50 is added to the flow circuit according to Fig. 1 in the conduit 14, as shown in Fig. 2. By means of said cut-off valve 50 and valve 19, the dialyser 17 or the hemofilter may be disconnected from the dialysis circuit. The conduit 20 and the pump 21 will thereby receive zero flow.

[0047] The flow which passes through the incoming channel 46 of the flowmeter 7 via the conduit 8 and 10 and reaches the outlet 11 must pass via the infusion circuit, i.e. the conduit 28, the pump 29, the conduit 30 and the infusion filter 31 and the conduit 33 to the drip chamber 34. By adjusting the dialysis machine to operate in this manner, the infusion pump 29 may be calibrated against the incoming channel 46 of the flowmeter 7.

[0048] If anything should throttle the flow through the infusion circuit, this will immediately be detected by the flowmeter 7 which shows zero flow despite the fact that the peristaltic pump 29 is rotating. In this manner, any incorrect priming with closed tube clamps may be

detected and identified.

[0049] Possible leakage in the pump 29 due to poor occlusion may cause flow through the pump 29 to become too low or high compared to the expected flow, which may also be detected by the flowmeter 7. In this case, the flowmeter 7 will show a higher value than expected from the rotational speed of the peristaltic pump 29, since there is normally a positive pressure at outlet 11.

[0050] In the same manner, an unsuitable tube set, an air-filled sterile filter, or blockage or leakage in the sterile filter can be detected as a difference between actual measured flow through the flowmeter and expected flow based on pump rotation.

[0051] All these conditions may be detected by the dialysis machine computer 70 and the computer may be programmed to undertake appropriate actions.

[0052] An alternative embodiment of the present invention is shown in Fig. 3. The valve 50 in the conduit 14 according to the embodiment shown in Fig. 2 has been replaced by a valve 51 arranged in the conduit 18. When activated, the valve 51 closes the conduit 18.

[0053] When the calibration of the infusion pump 29 is to take place according to the invention, the valve 15 is switched to its second position and the valve 51 is activated to its second position. In this manner, the dialyser 17 is completely disconnected. The flow in the dialysis circuit takes place via the bypass conduit 27. The flowmeter 7 thus notes that the incoming 46 and outgoing 47 flows are equal.

[0054] If, however, the infusion pump 29 is operated at a predetermined speed, for example to achieve an expected flow rate of 50 ml/min, the incoming flow 46 through the conduit 8 will be greater than the outgoing flow through the conduit 20, which is measured by the flowmeter 7. In this manner, the infusion pump 29 may be calibrated with the help of the flowmeter 7 by the difference between incoming and outgoing flows in the same manner as when ultrafiltration is measured. However, the difference which is measured according to the invention will be in the other direction, which does not, however, create any problems.

[0055] A pressure meter 45 may be connected at the outlet 11. The pressure meter 45 ensures that the conditions at the outlet 11 remain the same during operation irrespective of whether the dialysis machine is connected for the calibration of the infusion pump 29.

[0056] Fig. 4 shows the present invention applied to another type of dialysis machine in which the ultrafiltration is removed using a dedicated ultrafiltration pump 61 and in which the flowmeter 7 is adjusted such that incoming flow is always the same as outgoing flow. The pumps 6 and 21 as well as the flowmeter 7 may alternatively be replaced by a so-called balancing chamber, as is well known.

[0057] The ultrafiltration pump 61 is connected to the conduit 20 via a conduit 62. The ultrafiltration volume passes through the pump 61 and via a conduit 63 to an

outlet 64. In addition, a chamber 65 is arranged in the conduit 63 and is provided with a level regulator 66, 67. According to the invention, valve 51 according to Fig. 3 is used.

[0058] When the dialysis machine according to Fig. 4 is to be used to calibrate the infusion pump 29, valve 15 is switched to its second position and valve 51 is closed so that the dialysis flow passes from the conduit 14 to the bypass conduit 27 and further to the conduit 20. In this manner, the dialyser 17 or the hemofilter is isolated from the dialysis circuit. The ultrafiltration pump 61 must be stopped since identical flows pass through the incoming and outgoing conduits of the flowmeter 7.

[0059] As has been described above, a chamber 65 is connected in conduits 63 and encloses a volume of about 50 ml or more. When the infusion pump 29 is calibrated, the pump 61 is reversed at the same time that the pump 29 is started. The contents in the chamber 65 are pumped along the conduit 20 at the same time that the pump 29 is operated. In this manner, the flow which exits through the infusion pump 29 must be as great as the flow which enters via the pump 61 to the conduit 20. The flow through the dialysis circuit 8, 10, 14, 27, 20 still occurs with, for example, 500 ml/min and with equal flows through the incoming 46 and outgoing 47 channels or conduits.

[0060] Thus, the infusion pump 29 is calibrated against the reversed ultrafiltration pump 61. The solution which is in the chamber 65 is so-called dirty solution received from the dialyser 17. This solution will, however, be pumped into the conduit 20 and thereafter follow the flow through the flowmeter 7 to the outlet 23 and thus does not affect the clean side of the dialysis circuit in the conduits 8, 10 and 14.

[0061] If it is not possible to reverse the ultrafiltration pump, a valve package can be arranged instead which insures that the flow of the pump is reversed.

[0062] The calibration according to the invention preferably takes place at the commencement of a treatment during the priming step. During this first calibration, it may be established whether the flow through the conduit 28 is far too small, in which case an alarm signal is emitted.

[0063] It is also possible to calibrate the infusion pump 29 during operation of the dialysis machine. Normally, a self-calibration of the dialysis machine takes place approximately every thirty minutes during the entire dialysis process. Use of the method according to the present invention may be a part of such a calibration. If the embodiment according to Fig. 2 is used, the pump 21 is connected via the conduit 20, the valve 19 and conduit 18 to the dialyser 17. Thus, the pump 21 can assure that an underpressure prevails in the dialyser 17 which allows ultrafiltration to take place continuously even during the calibration. In this embodiment, the infusion pump 29 is calibrated with respect to the incoming channel 46 of the flowmeter 7.

[0064] If the embodiment according to Fig. 3 is used,

the dialyser 17 is completely isolated from the dialysis machine and no ultrafiltration takes place. However, an infusion of infusion solution in the blood occurs and liquid is thus supplied to the patient. However, the supplied infusion solution is of relatively small volume, in the order of 50 ml, which can easily be compensated for by increased ultrafiltration immediately after the calibration step.

[0065] It is to be understood that the invention can be adapted to use with dialysis machines having conduit paths different to that given above. It is, for example, possible to use the invention in a dialysis machine which lacks the filter 9.

[0066] The invention has been described above by reference to preferred embodiments depicted in the drawings. A skilled person recognises that these embodiments can be modified and adapted to different dialysis machines without departing from the spirit of the invention. The invention is restricted only by the appended claims.

Claims

1. A method for monitoring an infusion pump in a machine for hemodiafiltration or hemofiltration, whereby said machine comprises:
 - a first flow circuit for a dialysis solution;
 - a flowmeter arranged in said first flow circuit;
 - a second flow circuit for blood;
 - one of a dialyser or a hemofilter which, by means of a semi-permeable membrane, is divided into a first chamber connected to the first flow circuit and a second chamber connected to the second flow circuit;
 - a third flow circuit from an outlet for infusion solution in the first flow circuit to a connection in the second flow circuit and comprising an infusion pump;
 - characterized by
 - disconnecting the dialyser or hemofilter from the first flow circuit;
 - connecting the infusion pump in series with the flowmeter in the first flow circuit and monitoring the infusion pump by comparing the expected flow through the infusion pump with the measured flow through the flowmeter.
2. A method according to claim 1, characterized in that the flowmeter is constituted by a double flowmeter having portions for measuring incoming and outgoing flows and that the flowmeter portion for incoming flow is connected in series with the infusion pump.
3. A method according to claim 1, characterized in that the flowmeter comprises an ultrafiltration pump.
4. A method according to any one of the preceding claims, characterized in that the flow in the first flow circuit bypasses the dialyser or hemofilter via a bypass conduit, and in that the flowmeter determines the difference between incoming flow and outgoing flow in the first flow circuit.
5. A device for performing the method according to claim 1, for monitoring an infusion pump in a machine for hemodiafiltration or hemofiltration, whereby the machine comprises:
 - a first flow circuit for a dialysis solution;
 - a flowmeter arranged in said first flow circuit;
 - a second flow circuit for blood;
 - one of a dialyser or a hemofilter which, by means of a semi-permeable membrane, is divided into a first chamber connected to the first flow circuit and a second chamber connected to the second flow circuit;
 - a third flow circuit from an outlet for infusion solution from the first flow circuit to a connection in the second flow circuit, comprising an infusion pump;
 - characterized by
 - a first valve for disconnecting the dialyser from the first flow circuit and connecting the infusion pump in series with the flowmeter in the first flow circuit, and
 - an arrangement for monitoring the infusion pump by comparing the expected flow through the infusion pump with the measured flow through the flowmeter.
6. A device according to claim 5, characterized in that the first valve is arranged in a conduit which connects the outlet to the dialyser so that the flow in the first flow circuit ceases and all flow through the flowmeter also passes through the infusion pump.
7. A device according to claim 5, characterized in that the first valve is arranged in a conduit which connects the dialyser with the first flow circuit so that the dialyser is completely disconnected from the first flow circuit, and in that a second valve connects the dialysis flow via a bypass conduit past the dialyser, and an arrangement for monitoring the infusion pump by comparing the expected flow through the infusion pump with the difference between incoming and outgoing flows through the flowmeter.
8. A device according to claim 7, characterized in that the flowmeter comprises an ultrafiltration pump which supplies liquid to the first flow circuit, and in that the inlet flow and outlet flow in the first flow circuit are equal.

Fig. 1

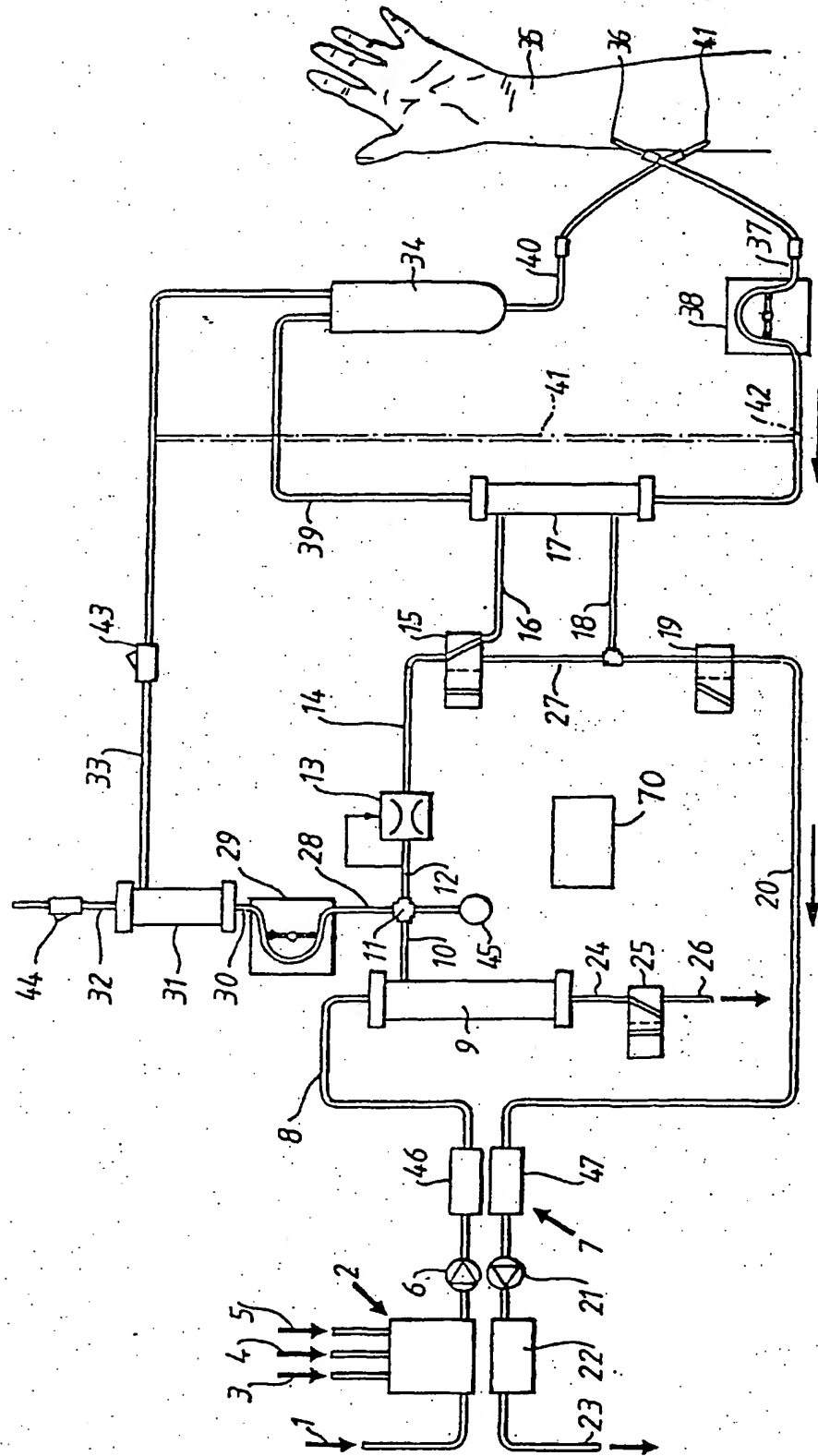


Fig. 2

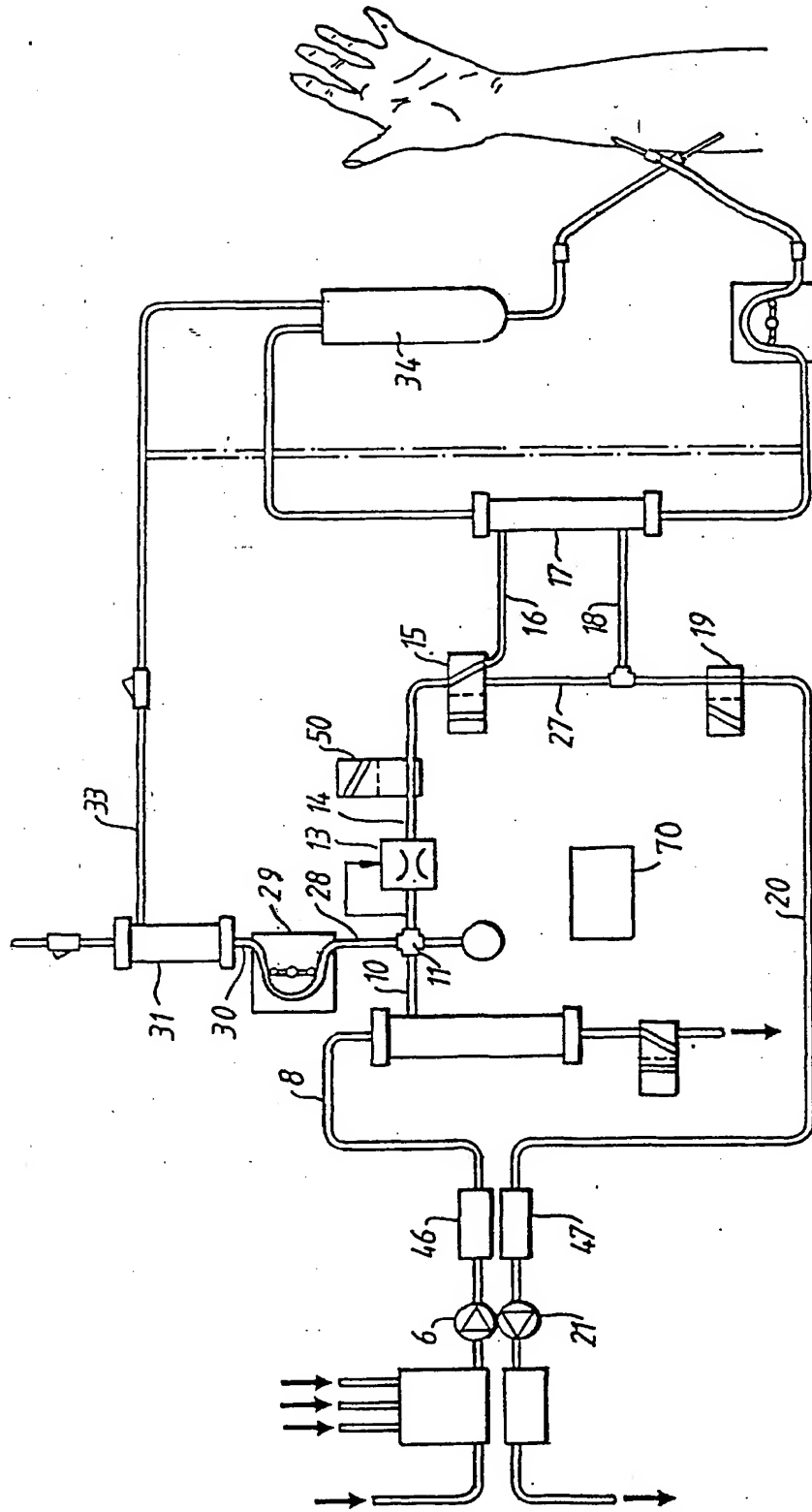


Fig.3

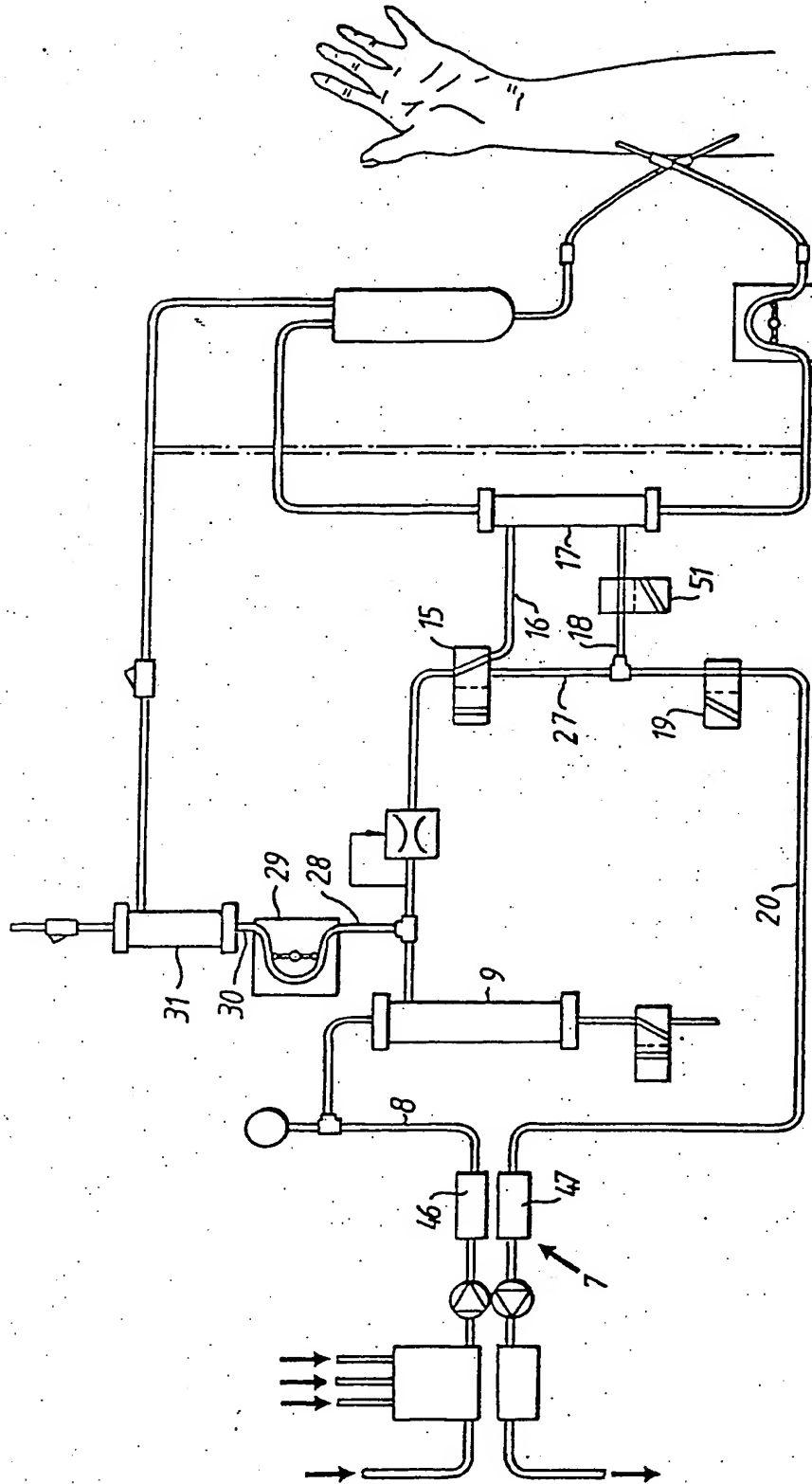
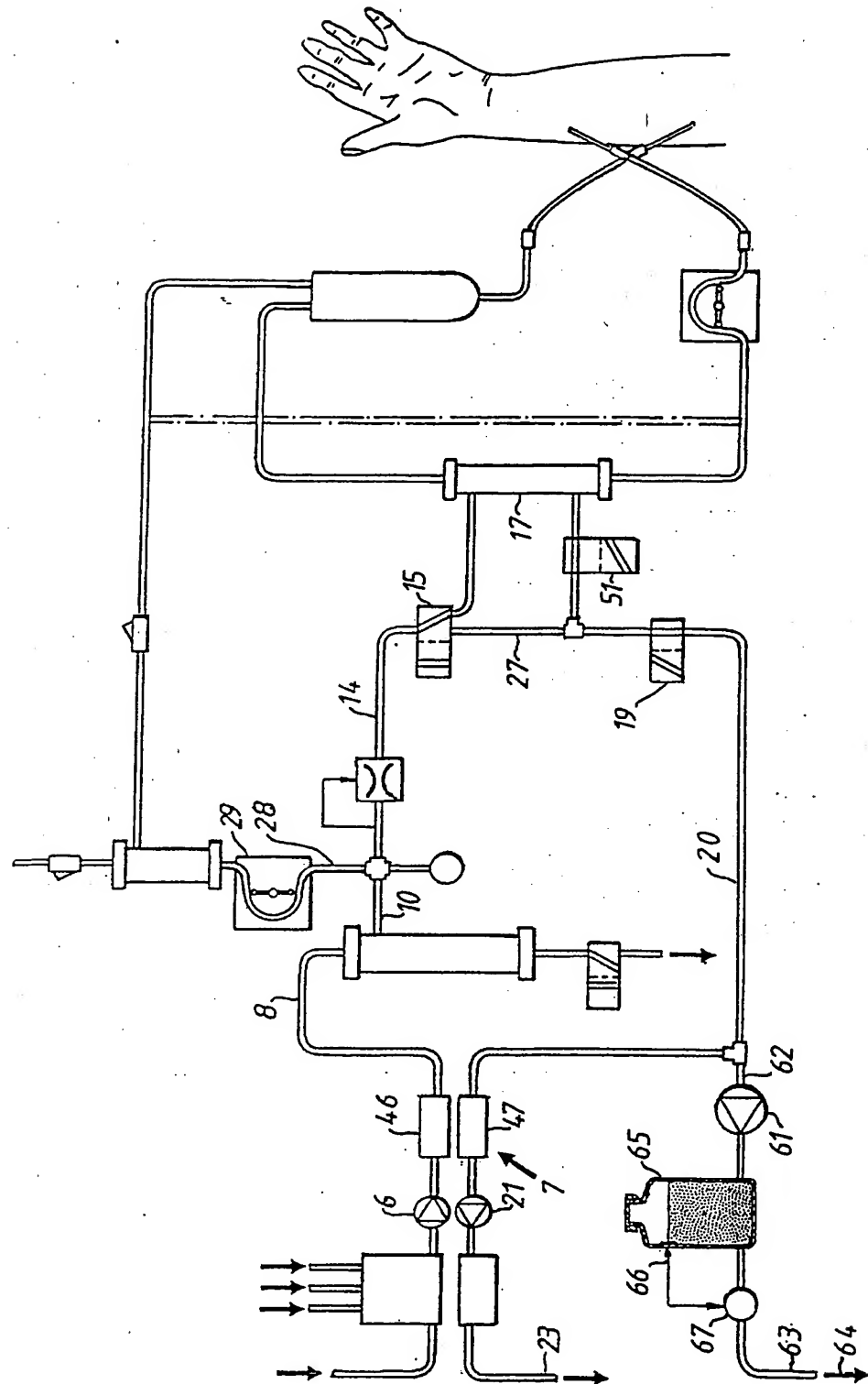


Fig. 4



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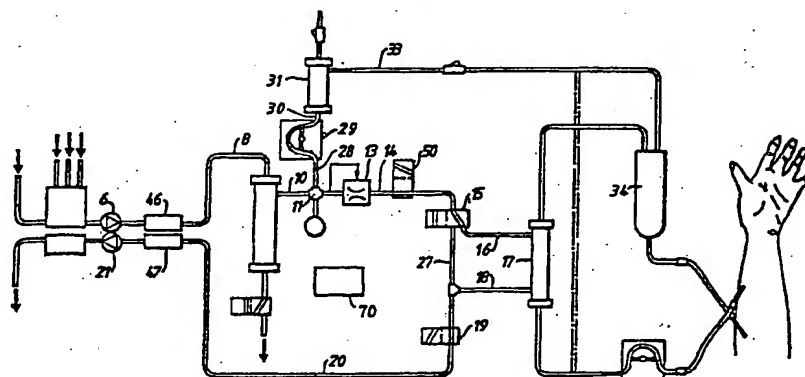
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solution in the first flow circuit to a connection in the second flow circuit and comprising an infusion pump. The dialyser is disconnected by means of a valve from the first flow circuit so that the infusion pump is connected in series with the flowmeter in the first flow circuit. The monitoring of the infusion pump takes place by comparing the expected flow through the infusion pump with the measured flow through the flowmeter.

Fig. 2



EP 0 904 789 A3



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EUROPEAN SEARCH REPORT

Application Number
EP 98 11 7720.7
Page 1

| DOCUMENTS CONSIDERED TO BE RELEVANT | | | |
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